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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,336	11/27/2006	Kenji Nagakawa	707550.000370	1215
29540	7590	07/05/2011		
DAY PITNEY LLP 7 TIMES SQUARE NEW YORK, NY 10036-7311			EXAMINER SAKELARIS, SALLY A	
			ART UNIT 1773	PAPER NUMBER
			NOTIFICATION DATE 07/05/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rschneider@daypitney.com  
kmcwha@daypitney.com  
psorge@daypitney.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,336	<b>Applicant(s)</b> NAGAKAWA ET AL.	
	<b>Examiner</b> SALLY SAKELARIS	<b>Art Unit</b> 1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-10 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-10, 16-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/13/2011 has been entered.

### ***Response to Amendment***

The amendment filed 6/13/2011 has been received and considered for examination. Claims 1, 2, 5-10, and 16-24 remain pending.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

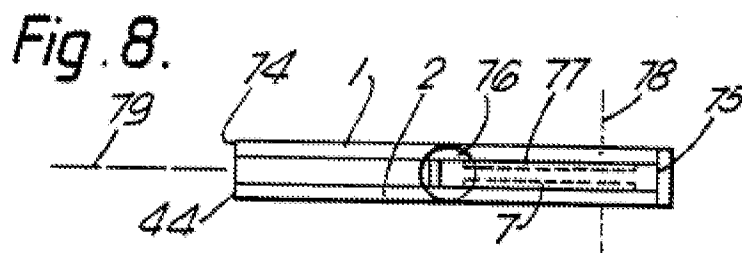
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-2, 5-10, and 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanks et al. (WO 86/00141) in view of Mochida (US 5147607) and in further view of Douglas et al. (US 5962215).

With regard to claims 1 and 16, Shanks teach an electrode free analyzing tool comprising: a reaction space in which a particular component of a sample and a reagent react with each other (within (1)) ; and a reagent portion ((7) and (77)) which is arranged in the reaction space (1) and which dissolves when the sample is supplied to the reaction space (1); wherein the reagent portion includes a first part (7) and a second part (77) facing each other, both capable of holding or retaining a reagent thereon and provided on a defining surface defining the reaction space (i.e., that space between (7) and (77) (Pages 23 and 24). It should be noted that the applicant's recitation of "is measured by colorimetry" in claim 16 will be interpreted by the office as intended use language but notwithstanding the device is interpreted as being capable of being detected with the use of colorimetry. Furthermore, it should be noted that Shanks teaches a color developing reagent in their immobilization and labeling with fluorescent ligands or dyes

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such as cibacrom blue, which specifically binds fluorescent and unlabelled albumin or other proteins (Page 11 lines 15-35) (Pg. 4 lines 1-15). Inherent in this teaching then is the substrate's capability for being detected with luminescent or colorimetric assays.



With regard to claim 1, Shanks does not teach that the color developing reagent of the first and second part is the same.

Mochida et al. teach redundant areas for sample detection using the same colorimetric reagent (See for example Figures 17a, 17b, and 17c). Mochida et al. teach that their reaction vessel having reagent immobilized areas (31) in position of an arc can be used with a series of variously diluted sample applications such that the substance in the test sample will be tested with the various dilutions of authentic samples allowing for an accurate and semi-quantitative assay to be carried out considering the color development of the redundant spots may be compared (Col. 14 lines 40-60).

It would have been obvious to a person of skill in the art at the time the invention was made to have used the same colorimetric reagent on both the first and second spots so that a second semi-quantitative test using a sample application of different dilutions could result, thus providing more information than just a single result including only the presence or absence of a particular compound and therein also a more precise result would be possible.

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Neither Shanks nor Mochida teach that the same colorimetric reagent on the first and second part is an oxidoreductase that is capable of reacting with the particular component for extracting electrons from the particular component and a same color-developing reagent that receives the extracted electrons for coloration.

Douglas et al. teach devices utilizing dry chemistry dye indicator systems for body fluid analysis. Specifically, Douglas teaches that the analyte reacts with a specific oxidase enzyme and produces hydrogen peroxide. Then, this strongly oxidative substance reacts with the indicator present to produce a colored end product (Col. 12 lines 47-67).

It would have been obvious to a person of skill in the art at the time the invention was made to have included the particular oxidase enzymes and indicators of Douglas et al. into the device of Shanks in view of Mochida et al. for the expected benefit that the incorporation of these dry chemistry reagents would enable a rapid, inexpensive, and accurate determination of various analytical protocols (Col. 1 lines 43-56) as opposed to those used in the Shanks in view of Mochida teachings.

With regard to claim 2, Shanks teach the first part (7) and second part (77) are separated from each other and that the first part and the second part differ in composition (Page 24 lines 334-36).

With regard to claims 5, 6, 16-19, Shanks teach the facing distance between (7) and (77) is taught to lie within a broad range of widths such as  $10\mu\text{m}$  –  $1000\mu\text{m}$  which includes widths that are therefore not greater than  $300\mu\text{m}$ ,  $150\mu\text{m}$ ,  $100\mu\text{m}$ , or  $75\mu\text{m}$  and not smaller than  $30\mu\text{m}$  (Pages 6 and 8).

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With further regard to claim 16, Shanks teach that the color developing reagent is capable of being dispersed into the sample and reaction space in their disposable, single use test device as they teach that their "reagents dissolves in the sample liquid drawn into the cell"(Pg. 22) and further considering the color reagent is capable of coming off of its anchored point following the sample's addition to the reaction space.

With regard to claims 7 and 22, Shanks teach the analyzing tool of claim 5 and 16 is further comprised by a first plate (7) and a second plate (77) both defining the reaction space and including respectively the first and second parts/regions (i.e., each part consists of a characteristic reactive layer, and if needed for the purposes of a particular test, an auxiliary reagent can be provided as a releasable coating that can dissolve in the sample liquid drawn into the cell) (Pg. 22 lines 4-26).

With regard to claims 8 and 23, Shanks teach the above structure includes a spacer (76) which defines the reaction space (i.e., that which is between (7) and (77)) creating the facing distance.

With regard to claims 9, 10, 20, 21, and 24 Shanks teaches that the blood is used as a sample which is moved through the microchannel by way of capillary action (Page 4, line 30-35 for example).

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2, 5-10, and 16-24 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SALLY A. SAKELARIS whose telephone number is (571)272-6297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 5712721267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sally A Sakelaris/

Primary Examiner, Art Unit 1773

6/29/2011